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Amendment
Serial No.: 10/612,784
Attorney Docket No.: ORW01-GN004

First, Applicant's specification provides proper basis for the limitation "wherein the augment material does not form scar tissue." The Examiner alleges that this limitation is new matter. Paragraph [0040] of Applicant's specification clearly recites:

In the exemplary embodiment utilizing the biologically reabsorbable snap-on augments 26, such augments 26 could be formulated to be absorbed over a relatively short period (i.e., several weeks or months) and *could also be formulated* so as to be replaced by tissue (such as scar-tissue) that would provide for long-term hip stability and, hopefully, normal motion. Such formulations of biologic materials are well known by those of ordinary skill in the art.⁴

From this disclosure, it is clear that not all of the augment materials disclosed transform into scar tissue. Thus, the specification acknowledges that some formulations of the augment material do not transform into scar tissue. Moreover, Applicant's disclosure at paragraph [0026] indicates that "biologically reabsorbable material" refers to materials that "degrade within, dissolve within, and/or be absorbed by the mammalian body." Paragraph [0026] says nothing about scar tissue formation. In view of the foregoing, Applicant's claims that recite augment materials not forming scar tissue are fully supported and not new matter.

Second, the specification fully supports the limitation of an acetabular liner with mating features, such as previously recited in claims 1, 27, and 109. The Examiner alleges that an acetabular liner with mating features is new matter, but fails to acknowledge that the bearing insert disclosed in the specification inherently has mating features. Those skilled in the art would well know this and evidence of these mating features may be found in U.S. Patent No. 4,695,282, for example. Nevertheless, Applicant has amended the pending claims to cancel this limitation to further prosecution.

⁴ Emphasis added.

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Third, the specification fully supports the limitation of an acetabular liner with at least one circumferentially oriented recess, such as recited in claim 110. The Examiner alleges that an acetabular liner with at least one circumferentially oriented recess is new matter. Applicant respectfully disagrees, but has cancelled claim 110 to further prosecution.

35 U.S.C. §§ 102, 103 Rejections

Claims 1, 2, 4-6, 14, 15, 27-32, 37, 109, and 110 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by German Published Patent Application No. DE 197 16 051 to Kluber ("Kluber"). In the alternative, claims 1, 2, 4-6, 14, 15, 27-32, 37, 109, and 110 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Kluber. These grounds of rejection are respectfully traversed.

With respect to claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109, Applicant is generally claiming a prosthetic device comprising at least an acetabular liner for releasably engaging an acetabular cup permanently mounted to the patient's pelvis, and a semiannular augment to be mounted to a rim of an acetabular liner of a hip replacement prosthesis, wherein the augment material is formulated not to transform into scar tissue. None of these claims is anticipated by Kluber.

A claim is anticipated only if each and every element is found, either expressly or inherently described, in a single prior art reference. See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); M.P.E.P. § 2131. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989); M.P.E.P. § 2131. Despite the Examiner's admission that Kluber fails to teach all of Applicant's claim limitations, the Examiner frivolously persists to allege that the pending claims are anticipated.⁵ For at least this reason, the §102(b) rejections of record are clearly in error and should be withdrawn.

Applicant can point to numerous limitations, at least one of which is recited, but not necessarily all are required, in each of the independent claims that are not taught by Kluber. Among these limitations found in at least one of the independent claims is an

⁵ See page 4 and 6 of the July 19, 2007 Office action.

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acetabular liner that releasably engages an acetabular cup permanently mounted the patient's pelvis. Kluber does not disclose an acetabular liner, but instead mounts his cup permanently to the pelvis. See FIG. 1 of Kluber and the absence of any acetabular liner. Further, Kluber only shows an acetabular cup, not an acetabular liner. Still further, unlike Applicant's claims, Kluber discloses mounting his ring to the acetabular cup, not the acetabular liner. Moreover, Kluber discloses that his ring forms scar tissue, which is precisely the opposite of what Applicant is claiming. It is immaterial that Applicant's augment material may contain PLLA, as PLLA in some form is disclosed by Kluber, because Applicant is claiming an augment material that goes away, whether or not it contains PLLA. The conclusory statements made by the Examiner, without a scintilla of support, that substances containing PLLA must act the same way in all circumstances is not supportable. The burden is not on Applicant to refute these statements; rather, the burden is on the Examiner to factually support them. In view of these omission from Kluber, only one of which is necessary for allowance of claims 1, 27, and 109, there is no reasonable basis to assert that Kluber anticipates any of the pending claims.

Further, claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109 are not obvious in view of Kluber. The Examiner alleges that Kluber renders obvious these claims, but does not address the factual considerations relevant to establishing a *prima facie* obviousness rejection. Office policy requires following *Graham v. John Deere Co.*,⁶ which includes: (A) Determining the scope and contents of the prior art; (B) Ascertaining the differences between the prior art and the claims in issue; (C) Resolving the level of ordinary skill in the pertinent art; and (D) Evaluating evidence of secondary considerations. Instead, all the Examiner recites is his summary, single sentence, conclusion as to obviousness is that any known bioreabsorbable material or combinations thereof would have been obvious. This statement falls woefully short of passing muster under Office policy. Nor does the portion of the Examiner's sentence referring to all of the other limitations Kluber allegedly renders obvious. Applicant respectfully requests the Examiner discuss in detail the rejections of record, if for no other reason that to ready the application for appeal.

⁶ See M.P.E.P. § 2141.

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As discussed in Applicant's most recent response, some of Applicant's claims recite a structure that may be used in revision surgery, which includes an acetabular liner and augments. In contrast, the device of Kluber is directed to a single-piece cemented cup with no modularity. Specifically, Kluber has no application in revision acetabular arthroplasty or with a system that is modular (i.e., using a replaceable socket liner) as recited in Applicant's claims, particular claim 1.

It should also be noted that claim 27 includes the limitation requiring the semiannular augment to include at least one *integrated* fastener. Nothing in Kluber discloses such a feature. Instead, Kluber relies on separate screws to mount the securing ring to the socket component.

Finally, as pointed out in the previous Office action and not disputed in the instant Office action, Kluber discloses that the PLLA is transformed into flexible native connective tissue, which the Examiner has interpreted as scar tissue. In direct contrast, Applicant claims an augment that does not transform into scar tissue, as the materials comprising the augment eventually dissolve completely so that no further support by the augment is provided to prevent dislocation after dissolution. Simply put, Applicant is claiming an augment that dissolves completely and does not transform into scar tissue, which is precisely the opposite of what Kluber teaches. In fact, the previous Office action itself concludes that those skilled in the art *would have wanted scar tissue formation*, which is in direct contrast with what Applicant is claiming. The Examiner's only rebuttal to Applicant's arguments is to point to an alleged contradiction with what Applicant previously thought. But Applicant has already shown this allegation to be erroneous.

The Examiner also persists to cite to M.P.E.P. § 2144.04 IV (C) for the proposition that those skilled in the art would have made the augment of Kluber into multiple, separate parts. Despite Applicant discussing *In re Dulberg*, which is cited to in this cited portion of the M.P.E.P., the Examiner continues to blindly cite this same M.P.E.P. section without ever bothering to consider Applicant's point. *In re Dulberg* was clearly shown to be inapposite to the instant situation of a single component allegedly cut into multiple pieces. Thus, *In re Dulberg* provides insufficient basis for the conclusory assertion that it would be obvious to those skilled in the art to cut apart any single

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component. Therefore, the Examiner's reliance on this M.P.E.P. section is clearly in error.

In light of the foregoing, the Office action is devoid of any objective factual basis to assert that the pending claims are anticipated or rendered obvious in view of Kluber. Reconsideration and withdrawal of the grounds of rejection as to claims 1, 2, 4-6, 14, 15, 27-32, 37, and 109 are respectfully requested.

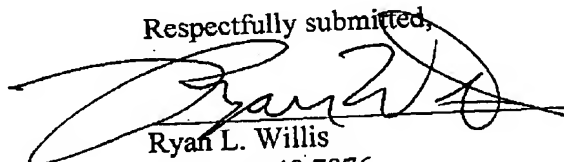
Conclusion

In light of the foregoing, it is respectfully submitted that claims 1, 2, 4-6, 14, 15, 27-32, 37-39, and 109, now pending, are patentably distinct from the references cited and are in condition for allowance. Reconsideration and withdrawal of the rejections of record are respectfully requested.

The Commissioner for Patents is hereby authorized to charge any additional fees that may be required by this paper, or to credit any overpayment to Deposit Account 50-3072.

In the event that the Examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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